NATIONAL TOBACCO REFORM INITIATIVE

Ending Cigarette Use by Adults in a Decade is Possible

August 22, 2022

Susan C. Winckler, CEO
Reagan-Udall Foundation
1333 New Hampshire Avenue, NW
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Dear CEO Winckler,

We recently learned that the Reagan-Udall Foundation has been asked by FDA Commissioner Califf to undertake a review of the Center for Tobacco Products. It has been over 12 years since the Family Smoking Prevention and Tobacco Control Act was signed into law In June of 2009 which established the Center for Tobacco Products. A great deal has changed in the years since the enactment of that landmark legislation. We believe that a great opportunity has arisen to review the operations of the CTP and to 'modernize' its regulatory framework to meet what is a rapidly changing tobacco/nicotine product environment. This includes not only things that can be undertaken within the Center under its current authorities but also changes that are needed for *modernizing* the statute.

The National Tobacco Reform Initiative (hereafter referred to as the NTRI) is an informal organization that was created about 8 years ago to try and push FDA and other public health organizations to focus more attention on helping adult smokers get off cigarettes. NTRI is led by a small group of distinguished, seasoned, and independent tobacco control leaders with decades of service, fighting the tobacco epidemic. The NTRI receives no financial assistance from any organization or outside entities, it is a completely voluntary effort. Over the past 8 years NTRI has advocated for *civil engagement* with all interested stakeholders and for open evidenced based discussion about the most effective ways to accelerate a reduction in the current number of adult smokers and associated diseases and premature deaths caused by smoking. One of the NRTI major priority areas has been to establish a more *rational, modernized and flexible* tobacco and nicotine framework that seeks to regulate products based on relative risks and which is adaptable to the increased speed of innovation in new technology of products that have the potential to displace deadly and addictive combustible products. Regulation, science, and technology, leading to new product entrants and ways to deliver products to consumers, shifting changes in consumers preferences, and competition are all playing a role in *reshaping* a rapidly changing nicotine product marketplace.

Recognizing that things were rapidly changing, former FDA Commissioner Scott Gottlieb, and former CTP Director Mitch Zeller announced and outlined a *new visionary comprehensive plan* in July of 2017—more

than five years ago. Unfortunately, the substance of that 'vision' has not been fully and openly discussed let alone implemented. The agency continues to struggle with an overwhelming workload using processes and tools that need to be streamlined and modernized. The plan laid out in 2017 needs to be revisited and would serve as a good starting point for the urgently needed modernization of the Center.

We would like to see the Center take a more proactive leadership role in providing or finding a 'neutral forum' where stakeholders could engage in civil dialogue and talk about the future in terms of both challenges and opportunities, not unlike what was done by the Institute of Medicine some twenty years ago when it released the landmark report "Clearing the Smoke". It is unfortunate that the current environment is almost toxic with policy and regulatory decisions appearing to be shaped not by scientific evidence as it should be, but more by political influence and often hyped in the press. Things must be done differently. With science and technology evolving at a rapid pace, it will be critical to ensure that there is openness, transparency, and civil engagement between stakeholders. The goal must always be improving both individual and population health.

When the CTP announced its July 2017 plan, it used such terms as 'crossroads' the need to encourage innovation, the need to regulate products based on the 'continuum of risk', the need to streamline its regulatory functions, the need to provide adult smokers with consumer acceptable lower risk affordable alternatives, the need to reduce nicotine levels in cigarettes to nonaddictive levels and of course the need to ensure that children and adolescents are not targeted or encouraged or have access to or use any nicotine product.

In the FDA's 2017 press release, the agency said:

> ***"Envisioning a world where cigarettes would no longer create or sustain addiction and where adults who need or want nicotine could get it from less harmful alternative sources, needs to be the cornerstone of our efforts-and we believe it is vital that we pursue common ground."***

Commissioner Gottlieb then went on to say:

> ***"To succeed, FDA must be strategic about how to use its tobacco and drug authorities. To succeed participants from all sectors in the ongoing harm reduction debate need to take a step back and work together to reach common ground."***

As the Foundation undertakes its efforts, here a few items and issues that we suggest the Foundation consider:

1. *Streamlining* review and approval processes that use a products standards approach for products that consider the risks and relative risk of the products. This might for example involve significantly modifying or eliminating the current excessive PMTA process and give manufacturers and the agency more continuity and consistency in regulating the broad spectrum of products.
2. Regulating product categories and products based on the *'continuum of risk'* which is designed to provide the public and users of tobacco and nicotine products with better consumer friendly information about the risks and relative risks of products—with the deadly combustible cigarette on the high end and with products like NRT, and other smokeless products, and e-cigarettes on the lower end. The FDA must strive to ensure that there is continuity, transparency, and coordination in regulating all tobacco and nicotine products. Like NRT

products, properly labeled and marketed very low risk noncombustible products could be flavored.

3. Eliminating excessive unnecessary regulatory barriers and costs that stimy and stifle 'innovation' and product development and that will promote competition in the development of new science- based lower risk products.
4. Undertaking an evidence -based public education campaign on *nicotine*- what it is and isn't (coordinated between the public and private sector). In spite of the fact that nicotine has been available to smokers for decades in the form of NRT (Nicotine Replacement Therapies) and without serious adverse effects, a majority of the public still believe that it is the nicotine that causes cancer and other harms. The confusion is in part unfortunately caused by misleading campaigns conducted by many organizations and individuals in tobacco control as well as misinformed policy makers at the local, state, and national level.
5. Developing better coordinated educational efforts that use science-based information and tools (including product labeling and marketing, social media etc.) and which should be embraced and implemented by all stakeholders. Users of tobacco and nicotine products should be entitled to full, complete, truthful, and accurate consumer-friendly information about the risks and relative risks of the growing spectrum of products.
6. Move forward with the reduction of nicotine in *combustible cigarettes* but done in parallel with providing users of tobacco with lower risk alternatives that are consumer acceptable, affordable, and accessible to those who would benefit from them.
7. Avoid the excessive risk aversion interpretation in applying the Appropriate for the Protection of the Public Health standard (AFPPH). An extreme application of this standard is doing more harm than good. A regulated product, properly labeled and marketed that is deemed to be significantly lower in risk than the deadly cigarette should be made available to the public and considered appropriate for the protection of the public health.
8. Work with all stakeholders (including manufacturers, retailers, public health entities and NGO's etc.) in developing coordinated and cooperative surveillance activities.
9. In order to accomplish many of the items noted above it is essential that FDA/CTP do a great deal more in initiating and encouraging dialogue between all stakeholders. This could be done through workshops, conferences, and advisory groups involving both public and private sector entities. CTP started down this kind of road under both Directors Deyton and Zeller, but it seems to have been totally abandoned for unknown reasons. Transparency and engagement by the CTP are critical to future successes in reducing the devasting toll caused on society by tobacco use both in the US and globally.

We are aware that you have already received a number of important letters, reports, papers etc. that will hopefully be of service to you and your staff's important work, in making the CTP a more efficient, 'modernized' operation.

We also wish to bring to your attention a **Citizens Petition** that was filed by the NTRI with the Center for Tobacco Products in March of 2020. Many of the issues and items noted in this letter were contained in the Petition. Many groups have provided comments on the Petition, although as of this date NTRI has not heard back from the CTP about the Petition other than acknowledging its receipt. Access to the Petition as well as the cover letter can be obtained through the NTRI homepage at https://www.tobaccoreform.org. As was noted in the cover letter:

This petition is intended to make recommendations to the agency for carrying out its responsibilities pursuant to provisions of the Food Drug and Cosmetic Act and specifically under the Family Smoking Prevention and Control Act and to consider ways of modernizing how it chooses to regulate a growing number of diverse tobacco and nicotine products. Specifically, we are urging FDA/CTP to establish a more flexible and workable regulatory framework that recognizes the opportunities associated with a rapidly evolving nicotine delivery marketplace, and to support stakeholder engagement and dialogue, which can better serve public health goals and objectives consistent with science-based comprehensive nicotine tobacco product regulatory strategies the agency outlined in 2017.

The NTRI and others stand ready to be available to you and your staff. Please feel free to call on us. If you have any questions about this request, please direct them to:

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Sincerely,

On behalf of the other members of the leadership committee of the National Tobacco Reform Initiative and other co-signers of this request:

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